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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,587	09/06/2001	Antonio Grillo-Lopez	27693-01186	5272

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WASHINGTON, DC 20005

EXAMINER	
DAVIS, MINH TAM B	
ART UNIT	PAPER NUMBER
1642	
MAIL DATE	DELIVERY MODE
02/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/762,587	GRILLO-LOPEZ, ANTONIO	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/08/08 has been entered.

Withdrawn Rejection

The Obvious-type Double patenting rejection over the application 10/196732 has been withdrawn, in view of that this application has been abandoned.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 7 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Maloney DG et al, 1997, Blood, 90(6): 2188-95, in view of Press et al, 1995, Lancet, 346 (8971): 336-340, Kaminski, MS et al, 1996, J Clin Oncology, 14(7): 1974-81, and Kaminsky et al, 1998, US 6,287537, and further in view of Wahl RL et al, May 1998, Proc Annu Meet Am Soc Clin Oncol,

17: 40a, abstract 156, from IDS # ZZZR of 04/06/04, for reasons already of record in paper of 12/07/07.

The response asserts as follows:

First, as argued in detail in the reply filed on 3 January 2007, the protocols reported in both the 1996 JCO article and the '537 patent were not designed to allow the experimenters to conclude whether or not any patients would have responded to a dose of unlabeled B1 antibody that would be expected to have therapeutic effect. In other words, there is insufficient information in the references to determine whether any patients in the trial could be categorized as "refractory" to a therapeutic dose of unlabeled B1.

Second, if Kaminski and coworkers had determined that some patients were refractory to unlabeled B1, then the express teachings of these references would not be logical. Specifically, Kaminski advocates - and the '537 patent claims - the use of an unlabeled CD20 antibody as a necessary step before the administration of an effective dose of radiolabeled CD20 antibody. See '537 claim 1, step (iii). If Kaminski considered that such a step had no effect, Kaminski would not have taught that it is advantageous to include it. The Office's finding is inconsistent with the teachings of the Kaminski references as a whole and cannot be relied upon to support its obviousness rationale. See M.P.E.P. § 2141.02, subsection Vl.

The response has been considered but is not found to be persuasive for the following reasons:

It is noted that “refractory” to treatment encompasses “not response to treatment”.

Kaminsky et al of the ‘537 patent teach that from observation of tumor responses, although non-labeled anti-CD20 antibodies by themselves exhibit some anti-tumor activity, there

are patients who do not response to non-labeled anti-CD20 antibodies, and that in these instances, their response only occurs after the largest dose (700mg) of non-labeled anti-CD20 antibodies, or only after a dose of radiolabeled anti-CD20 antibodies (column 21, lines 31-49). Although Kaminski et al of the '537 patent do not specify how to determine the non-responsiveness to non-labeled anti-CD20 antibodies in this particular observation, determining whether a subject having B-cell lymphoma is refractory, i.e. does not response, to treatment with an antibody is routine in the art, because tumor response evaluation is routine, in view of the teaching of Kaminski et al of the '537 patent and Maloney et al, and in view that the time interval for administration can vary substantially over a span of weeks, as taught by Kaminski et al of the '537 patent (column 10, lines 26-37). For example, tumor response can be determined from measurement of organ or tumor weight or size from physical examination, CT scan, tumor imaging, histological exam of tumor biopsies, before and after treatment with non-labeled anti-CD20 antibody, during the interval prior to treatment with the radiolabeled anti-CD20 antibody in view of the teaching of Kaminski et al of the '537 patent (Kaminski et al of the '537 patent, column 14, last three lines, column 16, second paragraph, and last two lines bridging column 17), or before and after treatment with the non-labeled anti-CD20 antibody in view of the teaching of Maloney et al (Maloney et al, p.2458, second column, last paragraph, p.2462). Kaminsky et al teach that for tumor response evaluation, a partial response is at least 50% reduction in the sum or the products of the longest perpendicular diameters of all measurable lesions and progressive disease is at least 25% increase or the appearance of new lesions (column 16, second paragraph). Kaminski et al of the '537 patent teach that two patients given subsequent trace-labeled doses preceded by a 685-mg unlabeled antibody predose is not assessable, because of **tumor response,**

that is, decreases in tumor volumes, occurring after these infusion (Kaminski et al of the '537 patent, column 17, lines 38-43). Maloney et al teach that histological examination of posttreatment samples remain diagnostic of lymphoma in the 7 patients (Maloney et al, p.2462, first column, lines 14th -16th), and that tumor regression occurred in 6 of 15 patients, with 2 partial and 4 minor response, wherein a partial response is at least 50% reduction in the size of the tumor and a minor response is 25% to 50% reduction in disease (Maloney et al, p.2458, second column, last paragraph).

Concerning claim 1 of Kaminski et al of the '537 patent, the teaching of Kaminski et al of the '537 patent is not inconsistent with the obviousness rejection. In claim 1, the use of the non-labelled anti-CD20 antibody prior to administering with the radiolabeled anti-CD20 antibody is for blocking non-tumor binding sites (item iii of claim 1). However, Kaminski et al of the '537 patent also observe that some patients response to said non-labeled anti-CD20 antibody alone, whereas some other patients do not response to the non-labeled anti-CD20 antibody until after administration of the radiolabeled antibody (column 21, lines 30-49, column 17, lines 31-43).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LARRY HELMS can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Minh tam Davis
February 3, 2009

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643